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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.
08/797,770	02/07/97	BAROFSKY	A	4430-18

020575 QM31/0520
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EXAMINER	
PREBILIC,P	
ART UNIT	**PAPER NUMBER**
3738	7

DATE MAILED: 05/20/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on April 6, 1998

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-24, 36-55, 74, and 76-99 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 1-24, 36-55, 74, and 76-99 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

It is noted that the election with traverse was affirmed in the amendment filed April 6, 1998, but the claims corresponding to the non-elected invention have been canceled.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

> It does not state that the person making the oath or declaration in a continuation-in-part application filed under the conditions specified in 35 U.S.C. 120 which discloses and claims subject matter in addition to that disclosed in the prior copending application, acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56 which occurred between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

Specifically, now that the specification set forth that the present application is a continuation-in-part to two other applications, the declaration needs to be reexecuted to include a reference to the parent applications.

Claims 15, 17, 21, 23, 49, 50, 51, 52, 54, 90, 92, 94, and 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In re claims 15, 21, 48, 54, 90, and 96, it is unclear how the intended use language of these claims is intended to further limit or modify the method of the base claim since the claims are drawn to a method of making.

With regard to claims 17, 50, and 92, it is unclear how the "stromal support matrix" is structurally related to the rest of the device as set forth in the base claim.

In re claim 17, it appears that "comprise" should be plural to be proper grammatically.

In re claim 49, line 2, "an" should be --a-- to be proper grammatically.

In re claim 23, the preamble is inconsistent with the claim body because the preamble sets forth a 'method of using a tropoelastin biomaterial', yet the claim body sets forth a 'method of making a tropoelastin biomaterial fused onto a tissue substrate'.

With regard to claim 51, it is unclear how the tropoelastin layer is related to the rest of the method set forth in the base claim.

With regard to claim 52, "a cells" is grammatically improper and it is unclear how the "cells" are related to the rest of the claimed device.

With regard to claim 94, "said cells" lack antecedence.

Claim 52 is objected to because of the following informalities:

The claim language uses improper Markush language; see MPEP 2173.05(h).

Appropriate correction is required.

The references struck from the enclosed PTO-1449 copy were already of record in the present application or copies thereof were not in either of the parent applications.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-24, 36-55, 74, and 76-99 are rejected under 35 U.S.C. 102(a) as anticipated by Gregory et al (WO 96/14807) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gregory et al (WO 96/14807) in view of Labroo et al (US 5,428,014).

Gregory et al is viewed as anticipating the present claims because the soluble elastin used therein is tropoelastin even though it is not called such in the disclosure because the elastin is uncrosslinked and unpolymerized elastin (i.e. this is definition of tropoelastin in the present specification); see the entire disclosure of Gregory et al.

Alternatively, one may not consider the claims anticipated by Gregory et al because tropoelastin is not explicitly stated therein. However, the Examiner posits that it would have been obvious to use tropoelastin as the elastin-like material of Gregory et al because it is so similar to elastin in tissue binding properties that it is considered interchangeable therewith; see Labroo et al

on Col. 9, lines 1-26. Furthermore, it is prima fascia obvious to use tropoelastin in the Gregory et al invention because it is an elastin-based material as required by Gregory et al.

Claims 47 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Rabaud et al (US 5,223,420) wherein the claimed process of tropoelastin polymerization reads on the Rabaud et al device because tropoelastin is disclosed in the present specification as elastin which is uncrosslinked and unpolymerized. Therefore, since Rabaud et al discloses an unpolymerized and uncrosslinked elastin which is crosslinked or polymerized with fibrin to form an elastin polymer, the Examiner posits that the claimed invention is anticipated thereby; see the whole document, especially the abstract and Col. 2, lines 3-10.

Claims 36-48 and 55 are rejected under 35 U.S.C. 102(e) as being anticipated by Schwartz et al (US 5,628,785) wherein the claimed process of tropoelastin polymerization reads on the Schwartz et al device because tropoelastin is disclosed in the present specification as elastin which is uncrosslinked and unpolymerized. Therefore, since Schwartz et al discloses an unpolymerized and uncrosslinked elastin which is crosslinked with fibrin to form an elastin polymer, the Examiner posits that the claimed invention is anticipated thereby; see the whole document.

Applicant's arguments filed April 6, 1998 have been fully considered but they are not persuasive. Specifically, the Applicant argues that Gregory et al (WO) is not available as a reference because it was invented by the same inventor. However, the Examiner notes that the present inventive entity as well as the descriptive subject matter related to tropoelastin is different in the Gregory et al (WO) and the US Serial No. 08/341,881 cases. Therefore, the Examiner

posits that the effective filing date of the present claims is May 31, 1996 or later and that the WO patent is proper prior art due to its earlier publication date and different inventive entity. For this reason, the rejection relying thereon is hereby maintained.

Applicant's arguments with respect to claims 36-48 and 55 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Weiss, can be reached on (703) 308-2702. The fax phone number for this Group is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.

Paul Prebilic

Paul Prebilic
Primary Examiner
Art Unit 3308